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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,033	07/11/2003	Yaron Keidar	50572/AW/W112	4112
23363	7590	07/14/2009	EXAMINER	
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			ART UNIT	PAPER NUMBER
			3734	
			MAIL DATE	DELIVERY MODE
			07/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/618,033	Applicant(s) KEIDAR, YARON	
	Examiner ERIN COLELLO	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,7-19,23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7-19,23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's amendment filed March 26, 2009. Claim 2 has been canceled without prejudice. Claims 1, 3-4, 7-19 and 23-24 are pending and an action on the merits is as follows.

Applicant's arguments filed March 26, 2009 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims **1, 3, 4, 7, 8, 13, 14, 15**, are rejected under 35 U.S.C. 102(b) as being anticipated by **Selmon et al. (US 6638247)**.

Regarding claims 1, 3, 4, 8, Selmon discloses a device comprising: an elongated, generally flexible tubular body having an axis, a proximal end, a distal end and a lumen longitudinally extending therethrough (Figures 3-6, (54)); and a dilating tip slidably mounted on the distal end of the tubular body (Figures 3-6, (50), (42)) and comprising a segmented surface that is generally transverse to the axis of the tubular body and comprises a plurality of segments having proximal and distal ends; wherein the segmented surface comprises two or more segments (Figure 6, (50)), a generally rigid tube extending distally from the segmented surface and having a sharp distal end

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adapted to puncture tissue (Figures 3-6, (42); Figure 14D, (296); Column 11, Lines 20-26; Column 17, Lines 34-51; wherein the tip (296) is sharp and capable of puncturing regardless of its disadvantages or intended uses);; wherein the rigid tube is segmented (Figures 3-6, (42)), a ring slidably mounted to the tubular body, wherein the distal ends of the segments of the segmented surface are hingedly attached to the ring; wherein proximal movement of the ring relative to the tubular body exerts a force on the segmented surface to thereby open the segmented surface (Figure 3-6, (64),(52); wherein ring (52) is sliding relative to the tubular body);

Regarding claim 7, Selmon discloses the dilating tip is generally funnel-shaped. (Figures 3-6, (50), (42))

Regarding claim 13, Selmon discloses that the dilating tip comprises nitinol (Column 12, Lines 35-40 and 59-65).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 9-12, 16 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Selmon et al. (US 6638247)**.

Regarding claims 9 and 10, Selmon discloses all of the claimed limitations above but fails to specifically disclose that the generally rigid tube of the dilating tip has

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a length ranging from about 2 mm to about 6 mm (wherein the range of 3mm to about 5mm falls within the range)

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the generally rigid tube of the dilating tip to have a length ranging from about 2 mm to about 6 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 11 and 12, Selmon discloses all of the claimed limitations above but fails to specifically disclose that the generally rigid tube of the dilating tip has an outer diameter ranging from about 0.6 mm to about 1 mm. (wherein the range 0.7 mm to about 0.8 mm falls within the range)

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the generally rigid tube of the dilating tip to have an outer diameter ranging from about 0.6 mm to about 1 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 16 and 23, Selmon discloses all of the claimed limitations above but fails to specifically disclose a latch for maintaining the position of the slidable member relative to the tubular body when the dilating tip is in an open arrangement.

However, the examiner considers latches to be well known for selectively maintaining the position of a wide variety of elements. Therefore, it would have been

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obvious to a person of ordinary skill in the art to modify Selmon's device to include a latch mechanism for maintaining the position, since such a modification would prevent the tip from undesirably opening and gives the operator control over the opening and closing of the distal tip.

5. Claims 14, 15, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Selmon et al. (US 6638247)** in view of **Wallace (US 6,254,628)**.

Regarding claims 14, 15, 18 and 19, Selmon discloses a device comprising: an elongated, generally cylindrical flexible tubular body having an axis, a proximal end, a distal end and a lumen longitudinally extending therethrough (Figures 3-6, (54)); and a dilating tip slidably mounted on the distal end of the tubular body (Figures 3-6, (50), (42)) and comprising a segmented surface that is generally transverse to the axis of the tubular body and comprises a plurality of segments having proximal and distal ends; wherein the segmented surface comprises two or more segments (Figure 6, (50)), a generally rigid tube extending distally from the segmented surface and having a sharp distal end adapted to puncture tissue (Figures 3-6, (42); Figure 14D, (296); Column 11, Lines 20-26; Column 17, Lines 34-51; wherein the tip (296) is sharp and capable of puncturing regardless of its disadvantages or intended uses); wherein the rigid tube is segmented (Figures 3-6, (42)), a ring slidably mounted to the tubular body, wherein the distal ends of the segments of the segmented surface are hingedly attached to the ring; wherein proximal movement of the ring relative to the tubular body exerts a force on the segmented surface to thereby open the segmented surface (Figure 3-6, (64),(52);

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wherein ring (52) is sliding relative to the tubular body). Selmon fails to specifically disclose a slidable member and a wire.

However, Wallace teaches the concept of controlling the distal movement of a retractable or sliding element from the proximal end of the device. Wallace teaches a pull tab connected to a pull wire that is connected to a pulling control mechanism on the proximal end of the catheter (Column 18, Lines 66-67; Column 19, Lines –3).

It would have been obvious to one of ordinary skill in the art to modify Selmon's device to include Wallace's pull wire and proximal sliding member, since such a modification would allow the operator to manipulate the action of the distal tip from a location proximal to the tip and possible outside the body.

6. Claims 17 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Selmon et al. (US 6638247)** in view of **Devos et al. (US 6,099,511)**.

Regarding claim 17 and 24, Selmon discloses all of the claimed limitations above but fails to specifically disclose a pressure valve at or near the proximal end of the tubular body.

However, Devos teaches a pressure valve at or near the proximal end of the tubular body (Figure 1, (30)).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Selmon's apparatus to include Devos's pressure valve, since such a modification would enhance the device by allowing the apparatus to measure different pressures.

Response to Arguments

7. Applicant's arguments filed March 26, 2009 have been fully considered but they are not persuasive.

- Applicant argues that the ends of the members are blunt and therefore are not sharp or capable of being adapted to puncture and that just because the member is pointed does not mean that it is sharp.

However, as addressed in the previous office action and reiterated herein, Selmon clearly indicates a sharp tip in Figures 14A-D alternative tips for use with anyone of the embodiments. Specifically, Figure 14D, (296) and Column 11, Lines 20-26; Column 17, Lines 34-51; wherein Selmon discloses that the tip (296) is pointed and capable of puncturing regardless of its disadvantages or intended uses; wherein by definition, point means sharp tapering end and therefore the arguments are not persuasive.

Furthermore, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex Parte Masham*, 2 USPQ F.2d 1647 (1987).

- Applicant argues that Selmon fails to suggest a ring slidably mounted on the tubular body, since component 52 is fixedly attached to the distal end of the catheter.

The Examiner respectfully disagrees. As pointed out in the rejection above, Selmon does in fact disclose a ring (Ref 52) slidably mounted on the

tubular body (Ref 54) which can be seen in Column 12, Lines 42-46 and therefore the arguments are not persuasive.

- Applicant argues that Selmon fails to suggest that the distal ends of the segmented surface are hingedly attached to the ring, since the components 64 are described as elbows which “allow space for deformation of the jaw sections 42 along an axis.”

The Examiner respectfully disagrees. As can be seen when comparing Figures 5 and 6, Selmon does in fact disclose that the segmented surfaces (Ref 42 and 50) are hingedly attached to the ring (Ref 52); wherein the hinge occurs where the reference character 64 is shown in Figure 6. Furthermore, Selmon discloses that the segmented spreading members are hinged in the brief description for Figures 5 and 6 which can be found in Column 8, Lines 63-67, “Figure 5 is a cross-sectional view of hinged spreading members shown in a relatively closed position.” And “Figure 6 is a cross-sectional view of hinged spreading members similarly illustrated in Figure 5 that are shown in a relatively open position and therefore the arguments are not persuasive.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIN COLELLO whose telephone number is (571)270-3212. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

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